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June 12, 2008
Date

Francis C. Hand

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte VINCENT L. VAILLANCOURT
and
PATRICIA VAILLANCOURT,
Appellants

Appeal No. 2008-1523
Application 10/773,538
Technology Center 3700

REQUEST FOR REHEARING

Sir:

This is a Request for Rehearing of the Decision on Appeal dated May 9, 2008 pursuant to 37 CFR 41.52.

1. It is respectfully submitted that Findings of Fact (FF) 1 and 2 set forth in the Decision are not in accord with Appellants' specification.

2. It is respectfully submitted that Findings of Fact (FF) 3 set forth in the Decision is not completely in accord with Appellants' specification.

3. It is respectfully submitted that Findings of Fact (FF) 6 set forth in the Decision is not completely in accord with Wemmert.

4. It is respectfully submitted that the Decision has misapprehended the requirements of claim 2 in light of the findings of fact and in affirming the rejection of claim 2 as unpatentable under § 103(a) over Wemmert for the reasons stated below.

I.A. Finding of Fact [1] is not in accord with Appellants' Application

One of the major advantages of the claimed product is the movement of the safety needle housing 101 into position before the needle is withdrawn from the patient. As a result, the sharpened point of the needle is never exposed. (Spec. pgs 11-12) [Fig. 27 of Appellants' application illustrates the needle when within a blood vessel of a patient.]

When used as an introducer needle (Seldinger technique), after placement of the needle in the patient blood vessel, a guide wire is threaded through the needle into the blood vessel as is conventional. Thereafter, the needle is removed from the patient and the needle guard immediately positioned over the needle tip. (Spec. p3) In another embodiment, the needle is conventional. At the proximal end of the plastic housing is secured a corrugated sleeve, which in the pleated state has a central hole. The sleeve is threaded through the needle thereby opening up the corrugations. The movement and locking of the needle within the plastic housing is similar to the embodiment previously described. (Spec. p 4)

As the housing 101 moves down the needle, the Mylar strip 110 unfolds about the needle until reaching its maximum extension. (Spec pgs. 10-11) [Fig. 24 illustrates the maximum extension of the Mylar strip.] The length of the Mylar

strip 110 is such that the housing 101 will enclose the sharpened end of the needle 12 before full extension is obtained. When full extension of the Mylar strip 110 is obtained and the needle is totally within the safety needle housing 101, the user releases the housing 101. At that time, there is some retraction of the Mylar strip 110 pushing the sharpened point of the needle against the lock 102. (Spec pg 11)

Thus, Fig 27 represents the position of the housing 101 when the needle is in a patient, i.e. the "first position", and Fig. 24 represents the position of the housing 101 after the needle has been withdrawn from the patient and the housing has been positioned over the end of the needle, i.e. the "second position".

Finding of Fact [1] is not in accord with Appellants' specification in finding that the needle guard is moved "from a first position [Fig . 24] where the sharp end of the needle is substantially enclosed to a second position [Fig. 27]" where the sharp end is exposed for use. That is say, the needle guard 101 is not moved from the position of Fig. 24 to the position to Fig. 27.

I.B. Finding of Fact [2] is not in accord with Appellants' Application

Finding of Fact [2] is not in accord with Appellants' specification for the same reasons as above.

2. Finding of Fact [3] is not completely in accord with Appellants' Application

Fig. 24 illustrates the safety needle housing 101 moved out from the initial position of Fig 27 and with the lock 102 positioned beyond the end of the needle

and prior to retraction of the Mylar strip 110. Fig. 24 represents the position of the safety needle housing 101 **after** the needle has been withdrawn from a patient. The needle cannot be reinserted through the lock 102 in the position illustrated.

3. **Finding of Fact [6] is not completely in accord with Wemmert**

The term "stretched" is not used in Wemmert.

Fig. 9 of Wemmert is a perspective view of a straight catheter and introducer needle assembly with the needle shield and tether prior to use (3:60-62). Fig. 7 illustrates the tether 44 prior to use in a collapsed condition (3:51-53).

Wemmert describes the use of the catheter and introducer needle assembly beginning at 7:7. That is, in order to place a catheter 21 into a patient's blood vessel, the clinician substantially longitudinally aligns introducer needle 31 and catheter 21 with the target blood vessel. The clinician then inserts introducer needle 31 and catheter 21 into the skin so that the sharp distal tip of introducer needle 31 enters the target blood vessel.

After confirming placement of the introducer needle 31 and catheter 21 in the target blood vessel, the clinician advances the catheter 21 along the introducer needle 31 into position in the blood vessel. After proper placement of catheter 21 is achieved, the clinician then withdraws the introducer needle 31 from catheter 21 by pulling needle hub 34 in a proximal direction (7:28-30). **Once the sharp distal tip of the introducer needle 31 is located within the main body portion 41 of the needle shield 40, continued proximal movement of needle hub 34 will result in a force sufficient to overcome the force holding fingers 47 to catheter hub 24 so that main body potion 41 [of**

the needle shield] can be removed from catheter hub 24. (See Fig. 4).(7: 29-35).

As explained beginning at 5:63, as the needle hub 34 is moved proximally with respect to the catheter hub 24, the needle shield 40 remains adjacent to catheter hub 24.

Wemmert describes the tether 44 as being relatively stiff so that when it is folded, it provides a slight biasing force to help maintain tether 44 in the completely extended position. This in turn aids in a maintaining needle shield 40 in position over the sharp distal tip of introducer needle 31 (6: 38-45). The tether 44 has a length that maintains the sharp distal tip of introducer needle 31 in main body portion 41 of the needle shield when the tether 44 is fully extended (5:65-6:1).

As can be seen from Figs. 1 and 2 of Wemmert, when the catheter 21 and introducer needle 31 are in a patient, the needle hub 34 is connected to the catheter 24. As shown in Fig. 2, when the introducer needle 31 is being withdrawn from the catheter 21, the needle hub 34 is disconnected from the catheter hub 24 and the needle shield 40 remains connected to the catheter hub 24 (fingers 47 include projections 48 to mechanically engage catheter hub 24 by a snap fit). (6:12-14). Hence, as the introducer needle 31 is withdrawn from the catheter 21, the tether 44 is unfolded into the position shown in Figs. 2 and 6 to extend between the needle shield 40 and needle hub 34.

There is no description in Wemmert that the tether 44 is "stretched" between the hub 34 and the shield 40. Citation 2: 63 reads "The needle shield is

connected to the needle hub by a tether that prevents the needle shield from being moved distally past the sharp distal tip of the needle." (emphasis added)

The citations at 4:48-50 and 5: 15-28 read as follows:

> "Introducer needle assembly 30 includes introducer needle 31 having a sharp distal tip defined by a bevel. The proximal end of the introducer needle 31 is connected to a needle hub 34."
>
> "As noted above, introducer needle assembly 30 also includes needle shield 40. Like catheter hub 24 and needle hub 34, suitable materials for needle shield include . . . Needle shield 40 includes main body portion 41, which defines a longitudinally extending passage 42 therethrough. . . . passage 42 allows introducer needle 31 to extend longitudinally through main body portion 41 . . ."

4. The Decision Has Misapprehended Claim 2 in Light of the Findings of Fact [1-3 and 6]

Claim 2 requires, *inter alia*, "a polyester film strip secured to and between said hub and said housing . . . whereby in response to a withdrawal movement of said needle relative to said housing, said needle moves into said housing and into abutment with said housing while said strip is stretched between said hub and said housing to retain said housing connected to said hub under a biasing force."

Claim 2 requires the needle to move into abutment with the housing whereas Wemmert has no teaching or description that the needle 31 abuts the shield 40. Instead, Wemmert teaches that the tether 44 is made of relatively stiff yet flexible material so that when folded into a pleated or accordion-like configuration, it provides a slight biasing force to help maintain the tether 44 in the completely extended position (6:38-44).That is to say, in the position

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represented in Fig. 6, the pleated tether 44 is in an outwardly biased condition that would space the needle out of abutment with the shield 40 as is so indicated in Fig. 6.

Claim 2 also characterizes the strip as being not only stretched between the hub and the housing but also stretched to retain the housing connected to the hub under a biasing force. Thus, claim 2 defines the biasing force not only as one that retains the housing connected to the hub but also as one that is effected by the stretching of the strip while the needle is in abutment with the housing.

It is respectfully submitted that there is no teaching in Wemmert that the shield 40 is connected to the needle hub 34 under a biasing force or that the tether 44 is stretched to retain the shield 40 connected to the hub 34 under a biasing force while the needle 31 is in abutment with the shield 40.

In summary, the rejections of claim 2 and dependent claim 3 as unpatentable under § 103(a) over Wemmert for the reasons stated above should not be sustained.

Respectfully submitted,

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